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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,518

10/07/2005

Kenji Yasuda

TIP 043

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23408

7590

09/25/2008

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EXAMINER

DOE, SHANTA G

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

09/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

garycohn@seattlepatent.com

Office Action Summary	Application No. 10/552,518	Applicant(s) YASUDA ET AL.	
	Examiner SHANTA G. DOE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/07/2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/07/2005 & 1/16/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on 1/17/2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4, 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 4, 6 and 7, these claims are indefinite because the examiner is not sure as to what the claim limitation "silicone-type

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resin” includes or excludes or encompasses. For examining purposes the examiner has interpreted the term “silicone-type resin” to mean any material containing silicon.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,632,656) in view of O'Connor et al(US 6,619,311).

Regarding claim 1, Thomas discloses a cell culture micro-chamber (6) comprising a cell culture section (cell growth chamber (2)), at least two channels(inlet channel (1) and outlet channel (5)) for connecting the cell culture section to the outside, and a means for optically observing (imaging apparatus with CCD camera, furthermore the device is transparent and hence one can visually observe cell culture section and the channel) the cell culture section and the opening or closing of the channels, wherein one of the channels (inlet channel (1) is a flow path through which a culture solution which may contain cells can be injected into the cell culture section, while another one of the channels (outlet channel (5) is a flow path through which a culture solution which may contain cells can be discharged from the cell culture section wherein the device further comprising a means of regulating flow in the channel or device (the flow can be regulated by making the channel hydrophobic wherein some parts are more hydrophobic than others or by changing the width or cross-sectional area of part of the channel along the channel) (see abs, fig 1 &3 col. 1 lines 66 -col. 2 line 4, col. 2 lines 17-19, 25-26, 61 -64, col. 3 lines 3-10,13-16, 27 – 40, 50-54,col. 4 lines 3-4; col. 5 lines 20 -24, 39-50 and col. 8 lines 40-48) .

However, Thomas fails to disclose that the cell culture device further comprises a means for opening or closing the channels and that at least a portion of said channels is surrounded by an elastic material.

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O'Connor et al (US 6,619,311) discloses a microfluidic device for biochemical analysis with a fluid flow control mechanism comprising channels which have opening and closing means associated with the channel and the channels comprise a elastic material (deformable membrane) within the channel wherein the material can be deformed either to open or to close the channel hence regulating the flow of fluid or material through the channel and /or chamber (see fig 3A – 3E, col. 3. line 65 – col.4 line 10, col. 4 lines, col. 5 lines 39-41 and col. 6 lines 20-25, line 46, col. 8 line 55-67, col. 9).

In view of (US 6,619,311), it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the channels in the device of Thomas with the channel in the device (US 6,619,311) which has a closing and opening means because the substitution of one known channel with a means of regulating flow of substances entering or leaving a device for another would have yielded a predictable result of having a channel which regulates the flow of substance into and out of a device.

Furthermore, the language “opening or closing the channels or altering the width of the channels by pressing or drawing the channels from outside in a direction substantially perpendicular to the observation direction of the means for optically observing” is intended use of the opening and closing means and the opening and closing means of the combined reference above is capable of such intended use.

Regarding claim 2, the combination above discloses a cell culture micro-chamber according to claim 1 wherein the width of the channels when not operating the

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means for opening and closing is on the same extent as the size of a target cell (when the deformable membrane is not deformed, it allows cells to pass freely (substance) through the channel to enter the cell culture chamber (called growth) hence the channel width has to be at least the width of the cells in order to allow passage of the cells)) .

1. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,632,656) in view of (US 6,619,311) as applied to claims 1 and 2 above, and further in view of Adey et al (WO/2003/015923) or Yun et al (US2005/0226781).

Regarding claims 3 and 5, the combination as applied to claims 1 and 2 above discloses a cell culture micro-chamber according to claims 1 and 2. The combination fails to disclose the device of claims 1 or 2 wherein the means for opening and closing has a space adjacent to the channels, the space being filled with a gas or liquid and the size of the space being altered by changing the pressure of the gas or liquid, whereby the channels are opened or closed, or their widths are altered.

Adey et al (WO/2003/015923) discloses channel/chamber comprising a deformable membrane (9 and 15) which has a opening and closing space (13) adjacent to the channels, the space being filled with a gas (air) and the size of the space being altered by changing the pressure of the gas, whereby the channels are closed or their width are altered (see abs, fig 1, page 3 lines 25-35; page 4 lines 1-10; page 5 lines 1-25) .

Yun et al (US2005/0226781) discloses chamber/channel having a deformable membrane(20) with an opening and closing means(30) disposed above the channel wherein the means for opening and closing has a space(90) adjacent to the channel, the space being filled with a gas or liquid and the size of the space being altered by changing the pressure of the gas or liquid (opened and close by an air pressure), whereby the channels are opened or closed, or their widths are altered(fig 1B & 3 [0028]-[0029] and [0011]).

In view Yun and Adey, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the closing and opening means of the combined reference with the opening and closing means as taught either by the Yun or Adey references, since the substitution of one known opening and closing means for another would have yielded a predictable result of deforming the deformable membrane to open or close the channel.

2. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,632,656) in view of (US 6,619,311) as applied to claims 1 and 2 above, and further in view of Miyazaki et al (US 2001/0002724).

Regarding claims 4 and 6, the combination as applied to claims 1 and 2 discloses the cell culture micro-chamber according to claim 1 and 2. The combination fails to specifically disclose that the elastic material is a silicone-type resin.

Miyazaki et al (US 2001/0002724) discloses that it is known in the art to have an elastic material made of silicone resin (see Miyazaki [0136]).

In view of Miyazaki, it would have been obvious to one having ordinary skill in the art at the time to have the elastic material of the combined reference be of a silicone-type resin as taught by Miyazaki, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al (US 6,632,656) in view of (US 6,619,311) and Adey et al (WO/2003/015923) or Yun et al (US2005/0226781) as apply to claim 3 above , and further in view of Miyazaki et al (US 2001/0002724).

Regarding claim 7, the combination as applied to claim 7 above discloses the cell culture micro-chamber according to claim 3. The combination fails to specifically disclose that the elastic material is a silicone-type resin.

Miyazaki et al (US 2001/0002724) discloses that it is known in the art to have an elastic material made of silicone resin (see Miyazaki [0136]).

In view of Miyazaki, it would have been obvious to one having ordinary skill in the art at the time to have the elastic material of the combined reference be of a silicone-type resin as taught by Miyazaki, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended

use as a matter of obvious design choice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANTA G. DOE whose telephone number is (571)270-3152. The examiner can normally be reached on Mon-Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GSD

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797